



TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number 09 883 093

Filing Date June 14, 2003

First Named Inventor Catherine Guenther

Art Unit 1632

Examiner Name Michael C. Wilson

Attorney Docket Number R-126

Total Number of Pages in This Submission

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ENCLOSURES (Check all that apply)

- | | | |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance Communication to a Technology Center (TC) |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input checked="" type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Petition | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declaration(s) | <input type="checkbox"/> Power of Attorney, Revocation | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Change of Correspondence Address | <input type="checkbox"/> Other Enclosure(s) (please identify below): |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | |
| <input type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Request for Refund | |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application | Remarks _____ | |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | | |

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Kelly I. Quast Reg No. 52 141
Signature	<i>Kelly I. Quast</i>
Date	July 9, 2003

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: July 9, 2003

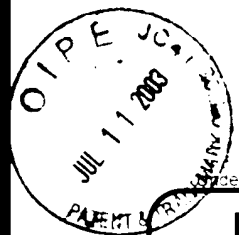
Typed or printed Don Mixon

Signature *Don Mixon*

Date July 9, 2003

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003 Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)
205.00

Complete if Known

Application Number 09 883,093
Filing Date June 14, 2001
First Named Inventor Catherine Guenther
Examiner Name Michael C. Wilson
Art Unit 1632
Attorney Docket No R-126

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METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account

Deposit
Account
Number
Deposit
Account
Name

50-1271

Deltagen, Inc.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee
to the above-identified deposit account

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X		
Independent Claims		-3** =		X		
Multiple Dependent						

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater. For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	2053	130	Non-English specification	
1812	2,520	2812	2,520	For filing a request for ex parte reexamination	
1804	920*	2804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	2805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	205.00
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	2451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (for reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	2460	130	Petitions to the Commissioner	
1807	50	2807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	2806	180	Submission of Information Disclosure Stmt	
8021	40	28021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	2802	900	Request for expedited examination of a design application	

Other fee (specify):

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)
205.00

SUBMITTED BY

(Complete if applicable)

Name (Print Type) Kelly L. Quast
Registration No. 52,141
Telephone 550-569-5100
Signature Kelly L. Quast
Date July 9, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FROM: Office of Initial Patent Examination

SUBJECT: Fee Due

APPLICATION NUMBER: _____

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A fee is due for the attached document submitted to the U. S. Patent and Trademark Office for the following reason. Please check the application for the appropriate authorization to charge a deposit account. If an authorization is present, please charge the appropriate fee. If an authorization is not present, notify the applicant of the fee deficiency.

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☒ No fee submitted per requirement

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Fee Due amount =\$ _____

If you have any questions, please contact Cynthia Streater at 703-306-5430 or Eleanor Kurtz at 703-308-3642.

Terminal Operator _____



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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 883.093	06 14 2003	Catherine Guenther	R-126	7936

7590 06 14 2003
DELTA GEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

12

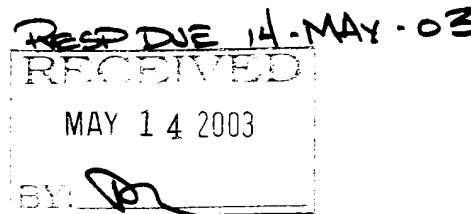
DATE MAILED: 04.14.2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/883 093

Examiner

Michael C. Wilson

Applicant(s)

GUENTHER ET AL

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35, 37 and 38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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DETAILED ACTION

The amendment filed 11-7-02, paper number 9, requesting replacement of Fig. 2A has not been entered. The amendment was not entered because enclosed new Fig. 2A did not have bracketing of nucleic acids found in original Fig. 2A and because a marked up version of the changes was not provided.

The amendment filed 12-11-02, paper number 11, was entered in part. The amendment to pg 8, lines 12-15, has been entered. The amendment to Fig. 2A has not been entered because the clean copy of Fig. 2A did not have bracketing of nucleic acids found in original Fig. 2A and because the clean copy and marked up copy of Fig. 2A do not match (the clean copy does not have bracketing while the marked up copy does have bracketing).

Sequence Listing

The application is in sequence compliance because the nucleotide sequence of Fig. 2A has been described in the amendment to pg 8, line 12-15, filed 12-11-02.

Election/Restrictions

Claim 36 has not been considered because it is unclear. Determining whether an agent modulates an abnormal spleen, thymus or lymph node using cells as claimed in the absence of an animal does not make sense. As such, a determination as to what group claim 36 belongs cannot be made. Therefore, claim 36 has been excluded from consideration in the restriction requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-4, drawn to a construct encoding two nucleic acid sequences homologous to a nuclear hormone receptor gene and a selectable marker, classified in class 435, subclass 320.1.

Group II, claims 5-7, 9, 13-15, 31 and 35, drawn to cells transfected with a vector encoding two nucleic acid sequences homologous to a nuclear hormone receptor gene and a selectable marker, cells having a disruption in a nuclear hormone receptor gene, cells isolated from a mouse having a disruption in a nuclear hormone receptor gene, and ES cells having a disruption in a nuclear hormone receptor gene, methods of using such cells to test agents, classified in class 435, subclass 325.

Group III, claims 8, 11, 12, 17-29, 32-34 and 38, drawn to a transgenic mouse having a disruption in a nuclear hormone receptor gene and a method of making such a mouse, classified in class 800, subclass 8.

Group IV, claims 10 and 30, drawn to a method of making transgenics having a disruption in a nuclear hormone receptor gene, classified in class 800, subclass 21.

Group V, claims 16 and 37, drawn to an agent that modulates a nuclear hormone receptor, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the cells of group II can be used to test cells *in vitro* while the construct can be used to make a probe. The cells do not require the construct and the construct does not have to be used to make the cells as they may occur naturally or by other means of mutagenesis. In addition, the

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construct does not necessarily disrupt a nuclear hormone receptor gene because it encodes at least two sequences that are homologous to a nuclear hormone receptor gene.

Inventions I and III are patentably distinct because the mouse of group III can be used as a model of disease while the construct can be used to transfect cells in vitro. The mouse does not require the construct and the construct do not have to be used to make the mouse. In addition, the construct does not necessarily disrupt a nuclear hormone receptor gene because it encodes at least two sequences that are homologous to a nuclear hormone receptor gene.

Inventions I and IV are patentably distinct because the construct can be used to make a probe while the method is used to make a disease model. The products and reagents required for a construct are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the nuclear hormone receptor gene in claim 10. The construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions I and V are patentably distinct because the construct can be used to make nuclear hormone receptor or to disrupt a nuclear hormone receptor gene while modulators of nuclear hormone receptor can be used to treat disease. The protocols and reagents for constructs and modulators are materially distinct and separate. The

construct does not require the modulators and the modulators do not require the construct.

Inventions II and III are patentably distinct because the mouse of Group III can be used as a model of disease while the cells can be used to isolate protein *in vitro*. The mouse does not have to be made using a transfected cell or an ES cell as it may occur in nature. A cell comprising the construct may not disrupt a nuclear hormone receptor gene because the construct does not necessarily disrupt a nuclear hormone receptor gene.

Inventions II and IV are patentably distinct because the cells can be used to test compounds *in vitro* while the method is used to make an animal. The products and reagents required for the cells are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the nuclear hormone receptor gene because the construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions II and V are patentably distinct because the cells can be used to study the function of nuclear hormone receptor while the nuclear hormone receptor modulators can be used to treat disease. The protocols and reagents for cells and modulators are materially distinct and separate. The cells do not require the modulators and the modulators do not require the cells.

Inventions III and IV are patentably distinct because the mouse can be used to make cells for an *in vitro* assay while the method is used to make an animal. The products and reagents required for the using the transgenic are materially distinct from those required to make a transgenic. The burden required to search both groups together would be undue.

Inventions III and V are patentably distinct because the mouse can be used as a model of disease while the modulator of nuclear hormone receptor can be used to treat a patient. The protocols and reagents for mice and for using a modulator to treat disease are materially distinct and separate. The mouse does not require the modulator and the modulator does not require the mouse.

Inventions IV and V are patentably distinct because the method can be used make a transgenic while the modulator of nuclear hormone receptor can be used to treat a patient. The protocols and reagents for making transgenics and for using a modulator to treat disease are materially distinct and separate. The method does not require the modulator and the modulator does not require the method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each of the groups is mutually exclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINE